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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,969	05/08/2001	Randolph J. Noelle	037003-0280613	1327

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	9

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/849969	Applicant(s) NOELLE
	Examiner GAMBEL	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 10/29/01

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 1-11

4a) Of the above claim(s) _____ is/are withdrawn from consideration. 3-11

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 1-2, 4-10

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☑ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

PAPER NO. 9

DETAILED ACTION

1. Applicant's election with traverse of the species diabetes in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the genus is relatively small. This is not found persuasive because of the reasons of record set forth in the previous Office Action (Paper No. 7). The species rare distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-2 and 4-10 are under consideration in the instant application.

Given that the instant claims only recite anti-gp39 antibodies as the antagonist of a receptor of a T cell, it is noted that the claims are read in light anti-gp39 targeting gp39 on a T cell.

If applicant amends the claims to recite other receptors or antagonists, then the claims will be subject to either species or restriction requirements.

Also, see the rejections under 35 USC 112, first paragraph, written description and enablement set forth below.

Applicant is invited to amend the claims to limit the active ingredient to anti-gp39 antibodies (anti-CD40L antibodies).

Claims 3 and 11 have been withdrawn from consideration as being drawn to the non-elected species.

2. No Information Disclosure Statement has been filed with this application.

3. Applicant should amend the first line of the specification to update the status of the priority documents.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention, including the use of anti-gp39 antibodies.

5.The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention, namely diabetes. Correction is required. See MPEP 608.01(b).

6. Formal drawings, filed 5/8/01, comply with 37 CFR 1.84.

7. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. It is apparent that 24-31 and 89-76 antibodies / hybridomas are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

Given the disclosure and the claims (e.g. see claims 3 and 16) encompassing the instant 24-31 and 89-76 antibodies and hybridomas set forth in Noelle et al. (U.S. Patent No. 5,747,037); the conditions for the deposit of biological materials under 35 USC 112, first paragraph, with respect to 24-31 and 89-76 antibodies / hybridomas have been satisfied.

Applicant is reminded that the following and should amend page 6 of the specification accordingly. The current address of the ATCC is as follows:
American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

10. This is a rejection under 35 USC § 112, first paragraph, "written description" (and not new matter).

Claims 1-2 and 4 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

There is insufficient written description encompassing any "antagonist of a receptor on a surface of a T cell which mediates contact dependent helper effector functions" other than targeting gp39 / CD40 ligand with anti-gp39 / CD40 ligand antibody (or the other gp39 Antagonists set forth on page 4, paragraph 1 of the specification) because the relevant identifying characteristics such as structure or other physical and/or chemical characteristics of said "antagonists" as well as the "receptor on a surface of a T cell which mediates contact dependent helper effector function" are not disclosed.

Applicant is relying upon certain biological activities and the disclosure of a particular receptor on a helper T cell" (i.e. gp39 or CD40 ligand) as well as certain known antagonists of CD40 ligand-mediated interactions (e.g., anti-CD40 ligand antibody, soluble CD40 /CD40lg) as limited representative species of to support an entire genus of receptors on T cells as well as antagonists. The instant invention encompasses any antagonist or T cell receptor that results in the desired binding and inhibitory effect, yet the instant specification does not provide sufficient written description as to the structural features of said antagonists and receptor that would provide a correlation between the chemical structure and the desired binding and inhibitory function.

The reliance on the disclosed gp39 / CD40 ligand and the known CD40 ligand antagonists of anti-CD40 ligand antibodies and soluble CD40 does not support the written description of any "antagonist" or "receptor on a T cell". It has been well known that minor structural differences even among structurally related compounds or compositions can result in substantially different biological or pharmacological activities. Structurally unrelated binding antagonists encompassed by the claimed "antagonists" would be expected to have greater differences in their activities. Further, the structure and mode of action of the CD40 ligand differs from other known and unknown T cell receptors that mediate contact helper dependent effector functions.

Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.
Thus, the specification fails to describe these DNA sequences. The Court further elaborated that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicant has not provided sufficient written description of any "antagonist of a receptor on a surface of a T cell which mediates contact dependent helper effector functions" as well as any "receptor on a surface of a T cell which mediates contact dependent helper effector functions.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

In the absence of structural characteristics that are shared by members of the genus of "antagonist of a receptor on a surface of a T cell which mediates contact dependent helper effector functions" as well as any "receptor on a surface of a T cell which mediates contact dependent helper effector functions"; one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

11. Claims 1-2 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of anti-gp39 / anti-CD40 ligand antibodies (and soluble CD40, which is not under consideration' see above), does not reasonably provide enablement for the use of any "antagonist of a receptor on a surface of a T cell which mediates contact dependent helper effector functions" as well as any "receptor on a surface of a T cell which mediates contact dependent helper effector functions" in the claimed methods to treat autoimmune diseases.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

There is insufficient disclosure does not enable any "antagonist of a receptor on a surface of a T cell which mediates contact dependent helper effector functions" as well as any "receptor on a surface of a T cell which mediates contact dependent helper effector functions" because there is insufficient direction and guidance as to the relevant identifying characteristics such as structure or other physical and/or chemical characteristics of said "antagonists" or "T cell receptors" capable of treating autoimmune diseases. Applicant has not provided sufficient biochemical information (e.g. molecular weight, amino acid composition, N-terminal sequence, etc.) that distinctly identifies or enables any "antagonists" or "T cell receptor". In

It is not sufficient to define a specificity by an ill-defined functional property or ambiguous structural properties. Also, an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property, that is, an "antagonist of a receptor on a surface of a T cell which mediates contact dependent helper effector functions" as well as a "receptor on a surface of a T cell which mediates contact dependent helper effector functions".

Therefore, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use of the claimed "antagonist of a receptor on a surface of a T cell which mediates contact dependent helper effector functions" to target any "receptor on a surface of a T cell which mediates contact dependent helper effector functions" in order to treat autoimmune diseases, commensurate in scope with the claimed invention.

Applicant is relying upon certain biological activities and the disclosure of a particular receptor on a helper T cell" (i.e. gp39 or CD40 ligand) as well as certain known antagonists of CD40 ligand-mediated interactions (e.g., anti-CD40 ligand antibody, soluble CD40 /CD40lg) as limited representative species of to support an entire genus of receptors on T cells as well as antagonists. The instant invention encompasses any antagonist or T cell receptor that results in the desired binding and inhibitory effect, yet the instant specification does not provide sufficient enablement as to the structural features of said antagonists and receptor that would provide a correlation between the chemical structure and the desired binding and inhibitory function in order to make and use antagonists of T cell receptors to treat autoimmune diseases commensurate in scope with the claimed invention.

The reliance on the disclosed gp39 / CD40 ligand and the known CD40 ligand antagonists of anti-CD40 ligand antibodies and soluble CD40 would not lead the skilled artisan to predict how to make and use any "antagonist" to target any "receptor on a T cell" to treat autoimmune diseases, commensurate in scope with the claimed invention. It has been well known that minor structural differences even among structurally related compounds or compositions can result in substantially different biological or pharmacological activities. Structurally unrelated binding antagonists encompassed by the claimed "antagonists" would be expected to have greater differences in their activities. Further, the structure and mode of action of the CD40 ligand differs from other known and unknown T cell receptors that mediate contact helper dependent effector functions.

For example, since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function.

The success of state of the art structure-based strategies for inhibitor design is highly unpredictable. For example, Kuntz (Science 257:1078-1082, 1992) on page 1080, column 3, discloses that as little as 2% of compounds predicted to inhibit specific enzymatic or receptor systems actually show inhibition in the micromolar range. Kuntz further discloses that "optimization" of these compounds has proven even more problematic. Therefore, in view of the unpredictability in the art, and in view of the insufficient guidance and working examples in the specification, the quantity of experimentation required by one skilled in the art to practice the invention undue.

Without such guidance, making and using the claimed "antagonist(s)" to target any "receptor(s)on a T cell" to treat autoimmune diseases would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. See In re Fisher, 166 USPQ 19 24 (CCPA 1970).

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1, 2 and 4-10 are rejected under 35 U.S.C. § 102(e) as being anticipated by Noelle et al. (U.S. Patent No. 5,683,693) (see entire document). Noelle et al. teach the use of gp39-specific / CD40L-specific antibodies, including chimeric and humanized antibodies (see columns 5-7, Antibodies) to treat the autoimmune disease diabetes (see entire document, including column 11, Uses of the Methods of Invention). Given the inhibitory properties of such gp39-specific / CD40L-specific antibodies, the prior art teach antibodies having the gp39 binding characteristics of the claimed 89-76 and 24-31 antibodies. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat autoimmune diseases, including diabetes with gp39-specific / CD40L-specific antibodies. A species will anticipate a claim to a genus. See MPEP 2131.02.

15. Claims 1, 2 and 4-10 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lederman et al. (U.S. Patent No. 5,993,816) (see entire document). Lederman et al. teach the use of 5C8-specific / CD40L-specific antibodies, including chimeric and humanized antibodies (see columns 7-8) to treat autoimmune diseases including diabetes (see column 11, paragraph 5). Given the inhibitory properties of such 5C8-specific / CD40L-specific antibodies, the prior art teach antibodies having the gp39 binding characteristics of the claimed 89-76 and 24-31 antibodies. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat autoimmune diseases, including diabetes with of 5C8-specific / CD40L-specific antibodies. A species will anticipate a claim to a genus. See MPEP 2131.02.

16. Claims 1, 2 and 4- 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Noelle et al. (U.S. Patent No. 5,683,693) AND/OR Lederman et al. (U.S. Patent No. 5,993,816) in view of Noelle et al. (U.S. Patent No. 5,747,037).

Noelle et al. ('693) and Lederman et al. are taught above and differ from the claimed invention by not disclosing the particular 24-31 and 89-76 CD40L-specific antibodies encompassed by the claimed methods.

Noelle et al. ('037) teach the particular 24-31 and 89-76 CD40L-specific antibodies encompassed by the claimed methods, including recombinant forms thereof as well as their use as therapeutic antagonists in inhibiting various immune responses (see entire document, including Detailed Description of the Invention).

Given the antagonistic properties of the particular 24-31 and 89-76 CD40L-specific antibodies taught by Noelle et al. ('037), the ordinary artisan would have been motivated to substitute these CD40L antagonists into the methods of treating autoimmune diseases such as diabetes, as taught by Noelle et al.('693) and Lederman, given their inhibitory properties were consistent with the antagonistic CD40L-specific antibodies taught by the prior art. Noelle et al. ('693), Noelle et al. ('037) and Lederman et al. All teach the advantages of anti-CD40L antibodies to inhibit immune responses by targeting the CD40L on T helper cells in therapeutic modalities of immunosuppression at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

17. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-2 and 4-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-26 of copending USSN 09/223,634. Although the conflicting claims are not identical, they are not patentably distinct from each other because each application is drawn to the same or nearly the same methods of treating autoimmune diseases such as diabetes with anti-CD40L antibodies alone or in combination with known inhibitors of autoimmune responses. It was well known and practiced at the time the invention was made to combine immunosuppressive therapies to treat the same condition with an expectation of success in achieving additive or synergistic immunosuppression.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-2 and 4-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,328,964. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims anticipate the instant methods.

20. No claim allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
January 8, 2003